

Flavors in E-cigarettes: Promise or Peril?

Saul Shiffman, Ph.D.

Senior Scientific Advisor, Pinney Associates
Research Professor of Psychology
University of Pittsburgh

Consult to Nicotivum, Reynolds Vapor, RAI (RJ Reynolds) on
smoking cessation, e-cigarettes, harm reduction

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Partner in JSR, LLC, smoking cessation medications

The Logic of Harm Reduction

- Smoking killing half of continuing smokers
- Alternatives need not be completely **safe** – but substantially **safer**
- Examples:
 - (Obvious) Methadone for heroin addicts
Needle exchanges for IV drug users
 - (Less so) Vaccines and medicines
 - Some patients are harmed

FSPTCA

Population Health Criterion

- The Act: .. *“For the protection of the public health, ..[based on] the risks and benefits to the population as a whole”*
- NOT perfection... NOT completely harmless, but
- Balancing risks and harms to achieve net positive public health benefit



Benefit and Harm in Different Populations

- Many population segments
- Two important extremes..
- Adult continuing smokers
 - Potential benefit
 - Benefit maximized with adoption – requires appeal
 - Stronger sensory appeal may mitigate need for pharmacological appeal
- Teen continuing nonsmokers
 - Potential risk
 - Avoid adoption – minimize appeal
- Flavors *thought* to differentially attract teens

Flavor Descriptors Study

- Objective:
 - Assess Adult Smokers' (**ADS**) and non-Smoking Teens' (**NSTS**) interest in e-cigarettes, and how it varies by flavors
- Samples
 - 216 NSTS (13-17, no tobacco use in 6 months)
 - 432 ADS (19-80, smoking, at least 3 years)
 - Source: Research Now online research panel

Procedures

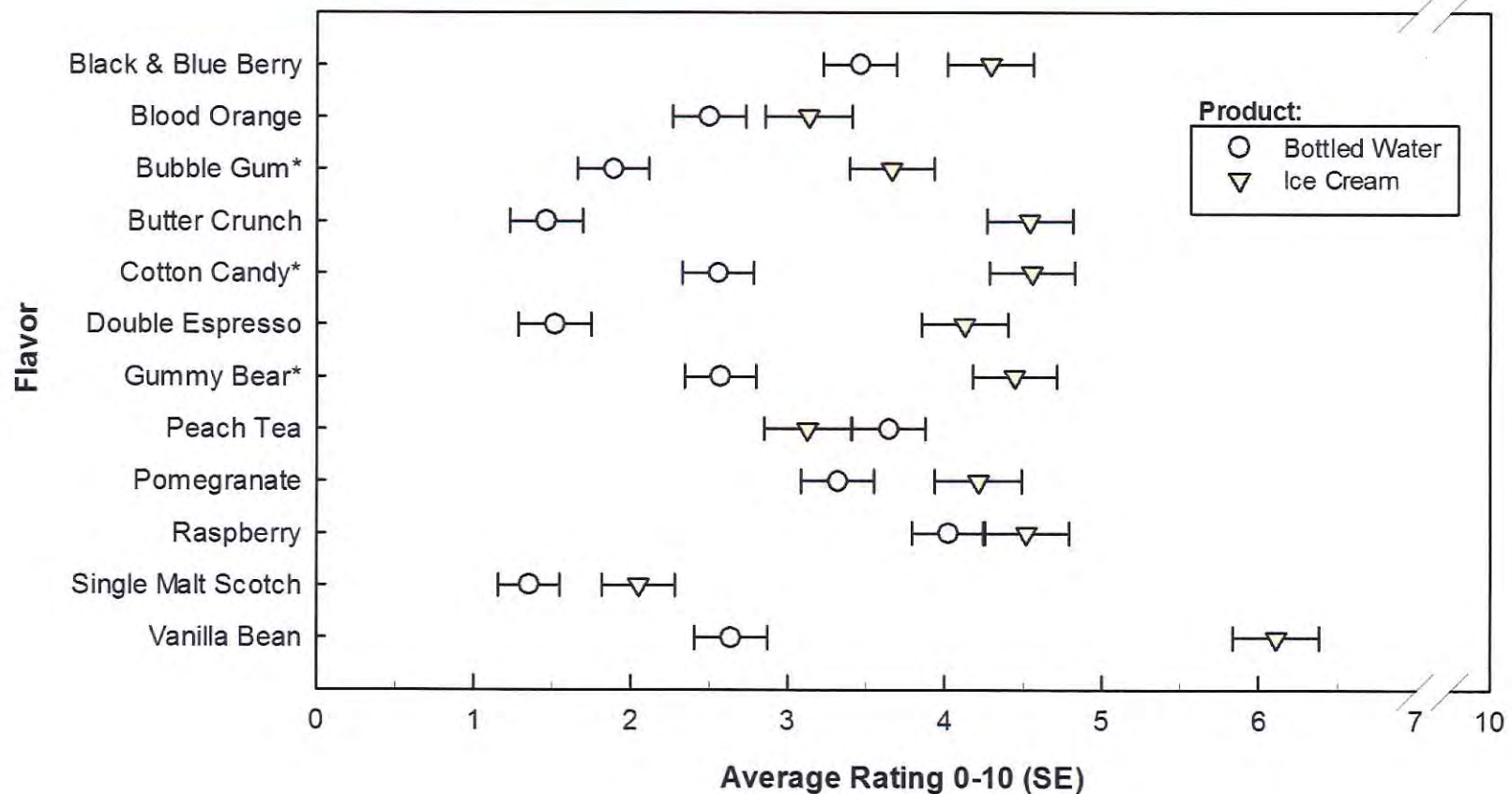
- Rated interest in using e-cigarettes in various flavors (0-10 scale)
- Interspersed with ratings of bottled water and ice cream, in same flavors (except tobacco)
 - Mask focus of the study
 - Test whether ratings sensitive to product, flavor

Flavor Descriptors Tested

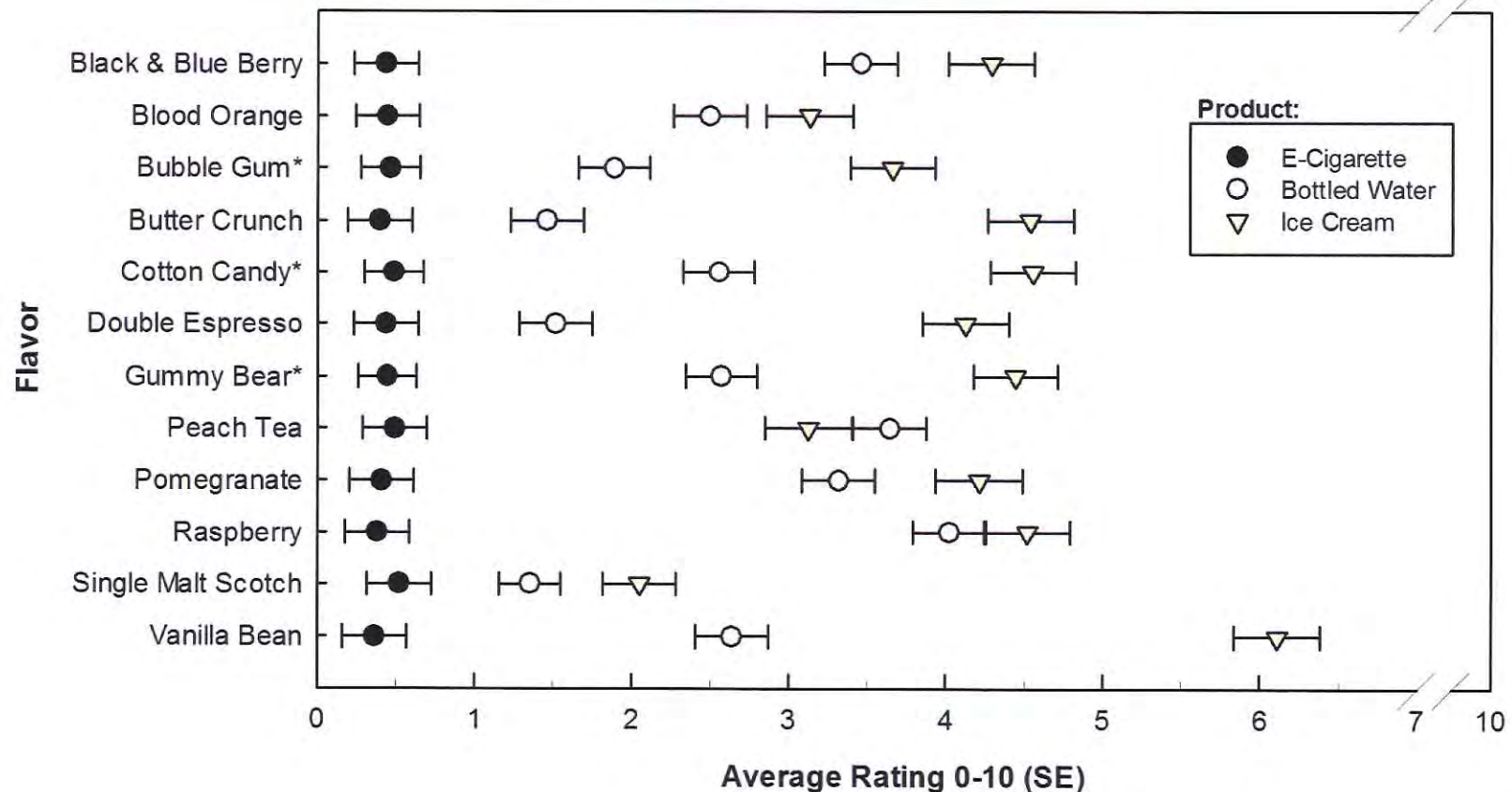
- Tobacco
 - Classic tobacco
 - Dark tobacco
 - Menthol
- Child-oriented*
 - Bubble gum
 - Cotton candy
 - Gummy bear
- Others
 - Blood orange
 - Butter crunch
 - Double espresso
 - Peach tea
 - Pomegranate
 - Raspberry
 - Single malt scotch
 - Vanilla bean

* Not under serious consideration

NSTs' Ratings Differentiate Products, Flavors

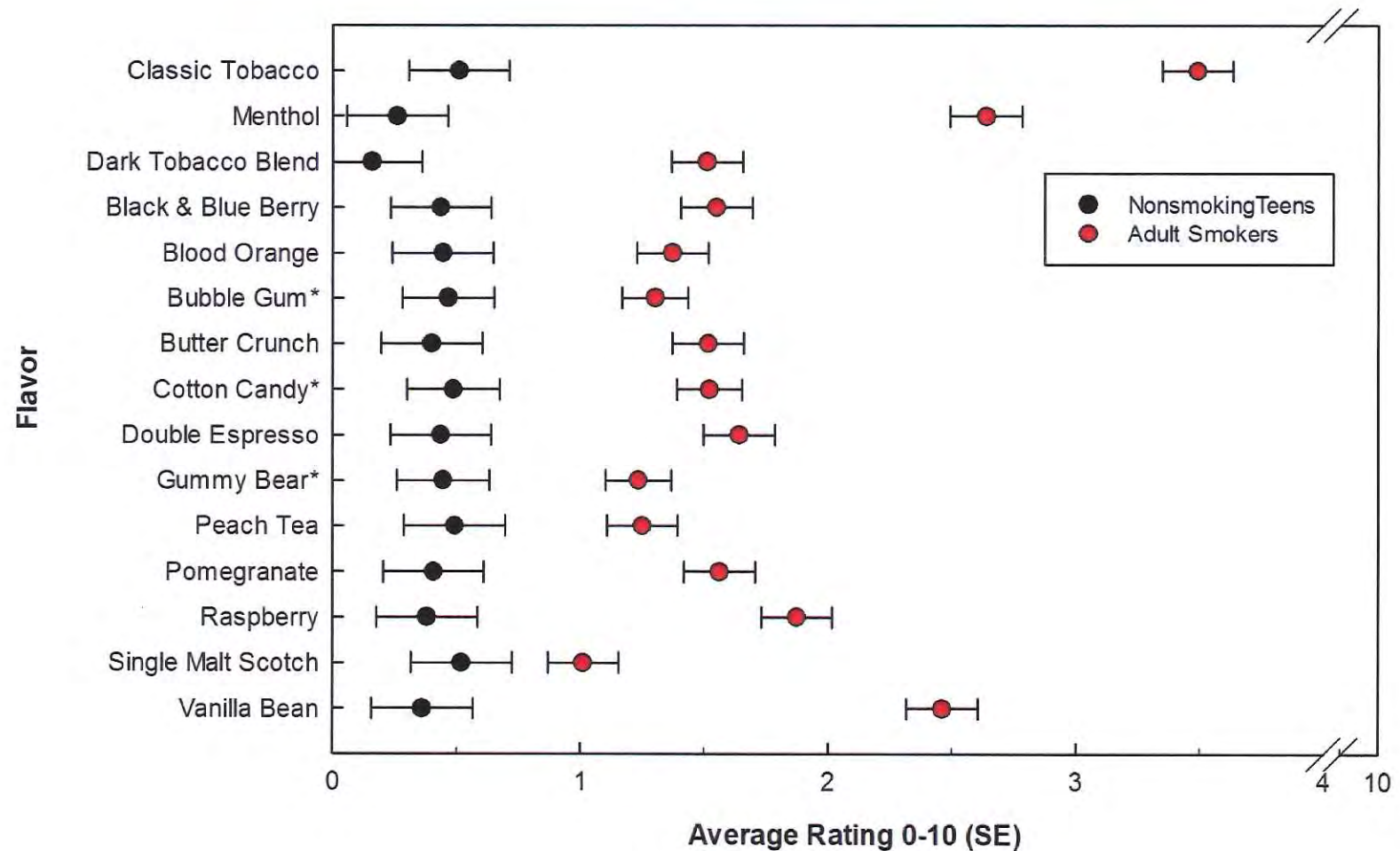


NSTs' Interest in e-cigarettes is Low, and Does Not Vary by Flavor

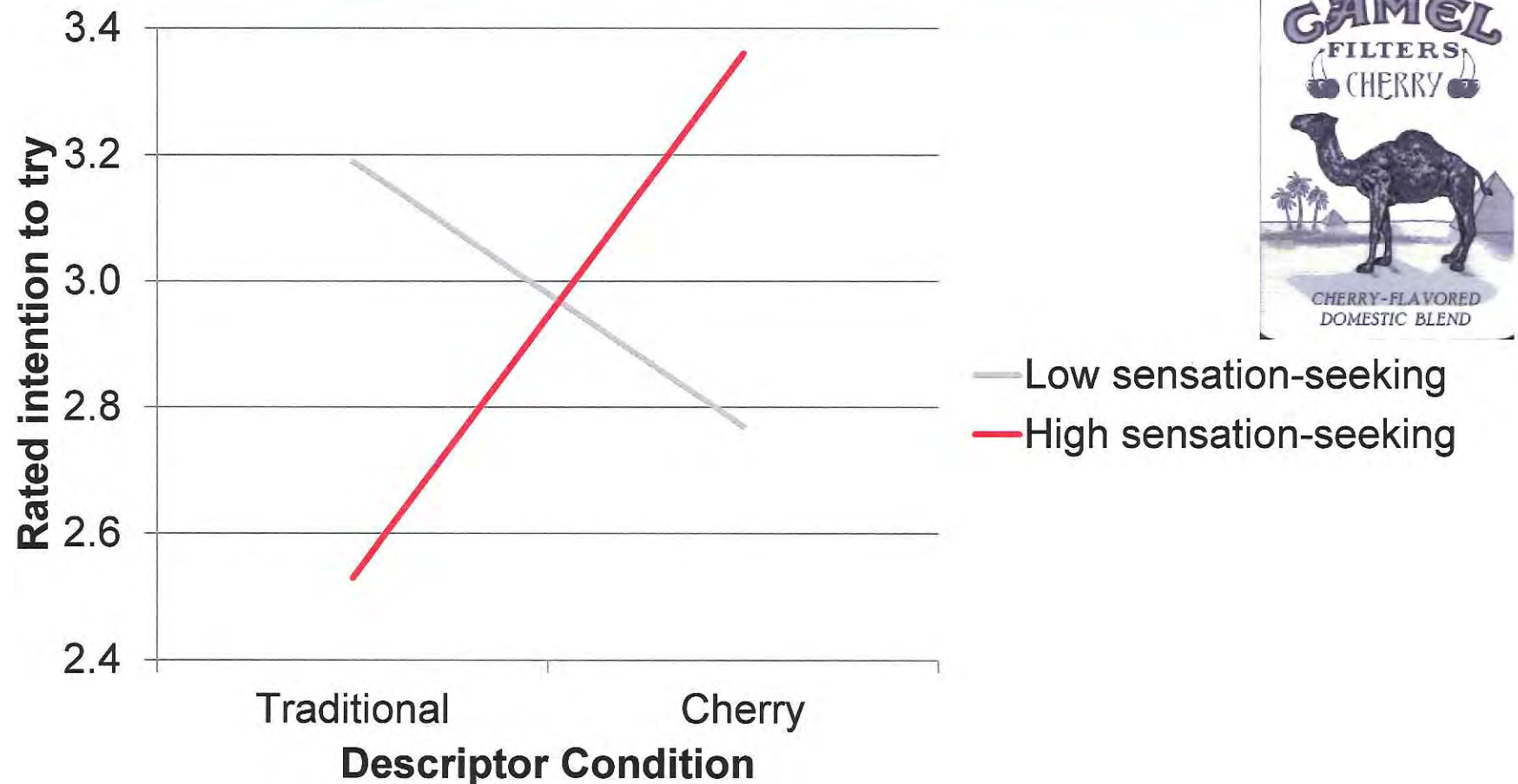


Pepper et al (2013) also found no effect of offering flavor on teen interest (n=228 boys, 11-19, rep. sample) 9

In Contrast, ADS' Interest in e-cigarettes is Higher, Varies by Flavor



Flavors in Cigarettes Appeal Primarily to High Sensation-Seekers

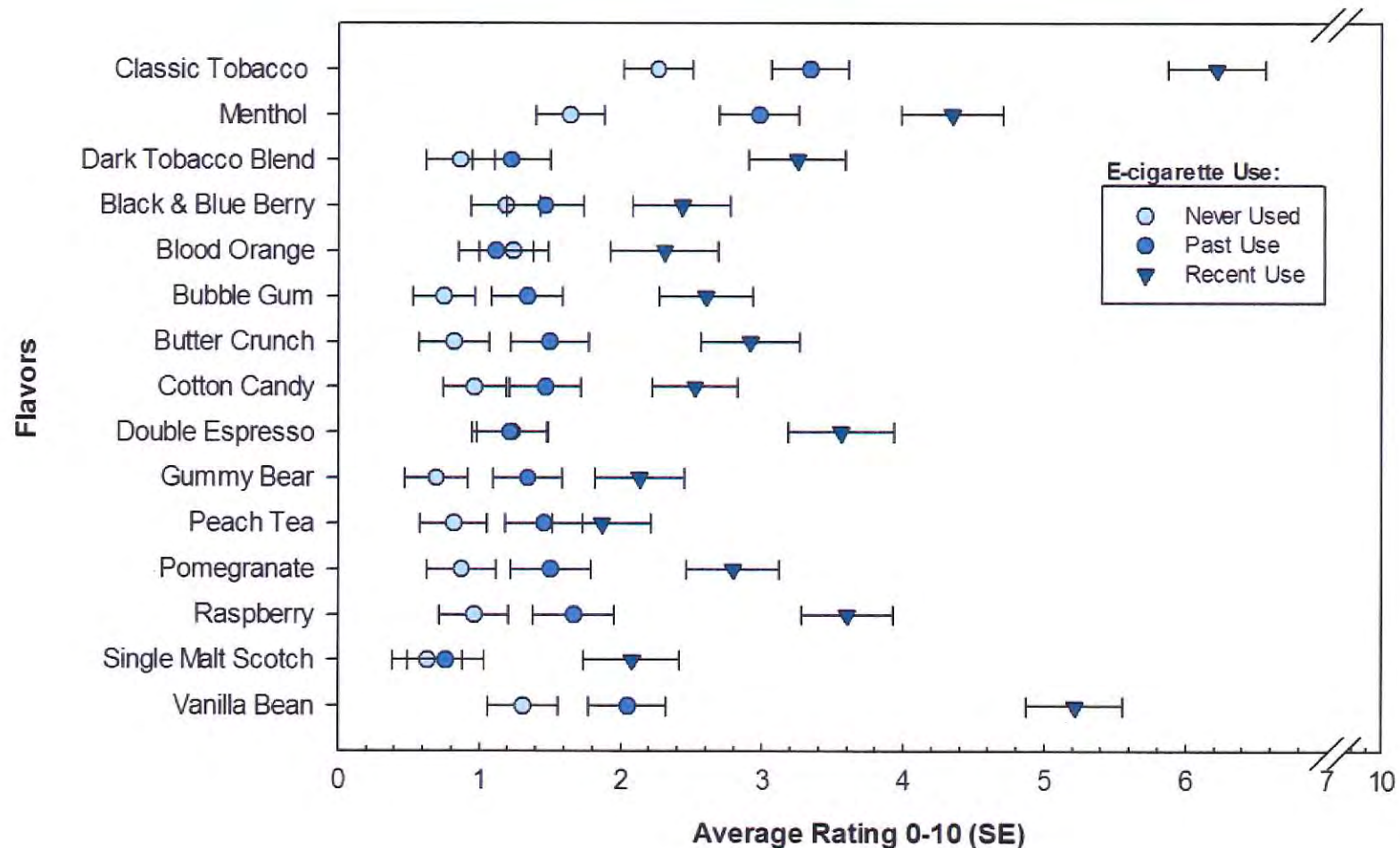


Manning et al, 2009, n=253 high school students

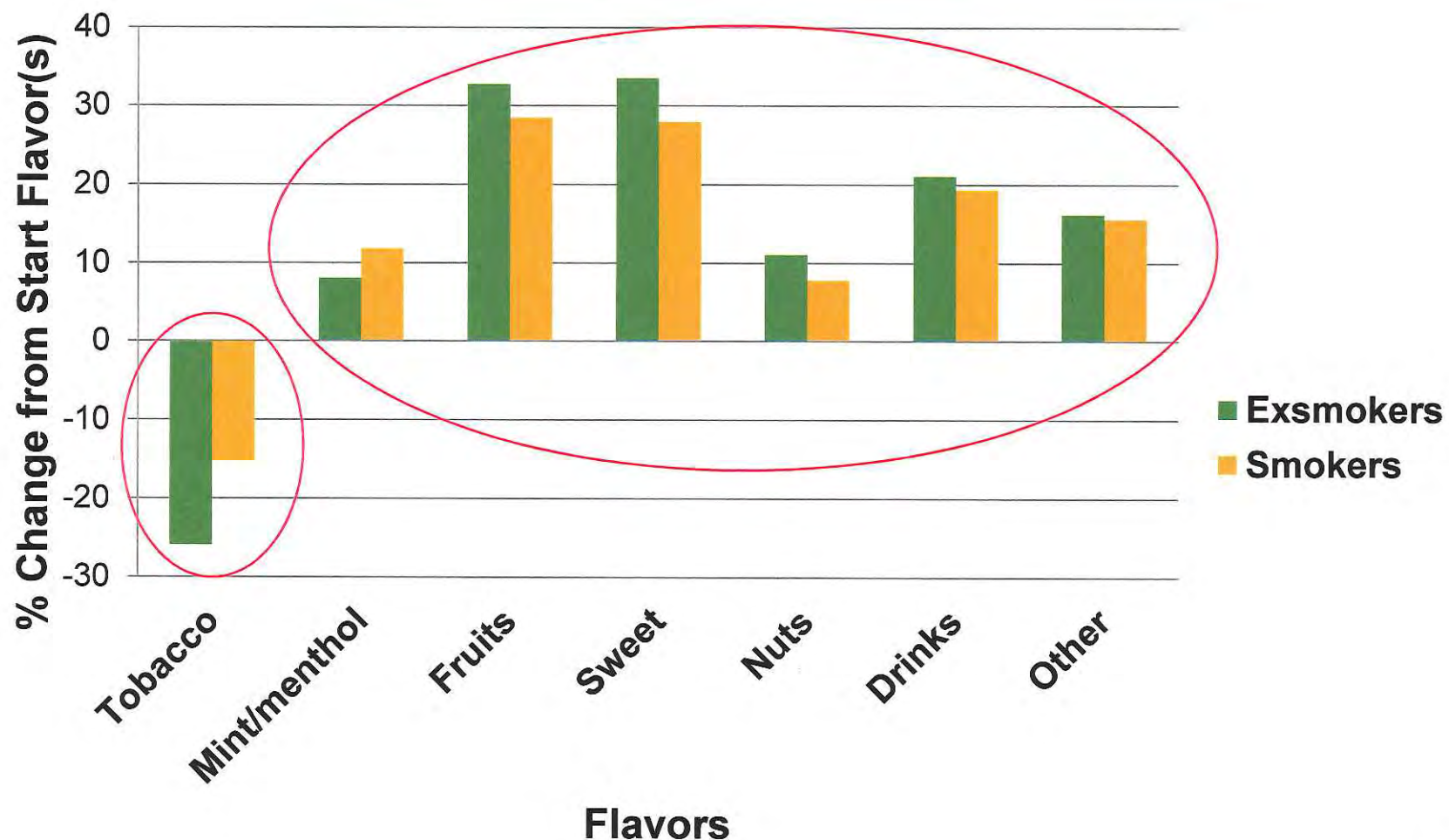
E-cigarette Flavors and Progression on Trajectory Away from Smoking

- In adult smokers, flavors do not just offer initial appeal
- Appear to be part of a pathway away from smoking to exclusive e-cigarette use

ADS' Interest in e-cigarettes and Flavors Increases with Progression of Experience



Changes in Vapers' Flavors Used, From Starting to the Present



Methodological Considerations


- Studies two informative groups, not full population
- Rating flavor descriptors, not tasting flavors
 - But that is what initially appeals...and concerns
 - That is how flavor effects have been assessed
- Single rating of interest in use
- Online panel samples, may not be fully representative
- Adult sample weighted to age profile of US smokers
- Study focus was masked to minimize bias
- Stimuli randomized and counter-balanced
- Methodology check in ratings of other products
- Findings clear

Appeal, Use, and Public Health

- A harm reduction product that is not used produces no public health benefit
- Appeal – to the right target population – is a public health good
- Appeal of alternatives to combustion products is essential to harm reduction
 - Flavor
 - Esthetics
 - Price
 - Convenience

INNOVATIONS IN BUILDING ConsumerDemand

- View smokers as consumers and taking a fresh look at products from their perspective.
- Redesign products to better meet consumers' needs and wants.
 - Design aesthetically pleasing products that create a positive and compelling consumer experience.
 - “Lower the bar” to make the initial trial easy and less costly
- Market and promote products in ways that reach smokers where they are.
- Seize policy opportunities for “breakthrough” increases in use and effectiveness.



Under the FSPTCA... the FDA Center for Tobacco Products (CTP) is able to bring science-based regulation to ... tobacco

FDA Commissioner Margaret A. Hamburg, M.D.

FDA press release, September 19, 2013

Research ... will be used ... as the foundation for our policies.

CTP website

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/ucm383161.htm>



shiffman@pinneyassociates.com
shiffman@pitt.edu

THANK YOU